Serial No.: 09/938,667 Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE

AND VESICOURETAL REFLUX

Page 2 of 13

In the Claims:

Please amend the claims as follows:

1. (Currently amended) A bio-stable hydrogel comprising the combination of acrylamide and methylene bis acrylamide in amounts to provide about 0.5 to 25% by weight polyacrylamide of a polymer, based on the total weight of the hydrogelwherein hydrogel, the polymer consisting essentially of a polymer prepared from combining acrylamide and methylene bis-acrylamide, wherein said biostable hydrogel is in a form suitable for the treatment of incontinence and or vesicouretal reflux; and is substantially free of wherein said bio-stable hydrogel includes less than 50 ppm monomeric units.

- 2. (Currently amended) The hydrogel according to claim 1, wherein said eombination polymer of acrylamide and methylene bis-acrylamide is obtained by combining the acrylamide and the methylene bis-acrylamide in a molar ratio of 150:1 to 1000:1.
- 3. (Currently amended) The hydrogel according to claim 1, comprising less than 15% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.
- 4. (Currently amended) The hydrogel according to claim 1, comprising at least 1% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.
- 5. (Previously presented) The hydrogel according to claim 1, having a complex viscosity of about 2 to 40 Pas.
- 6. (Previously presented) The hydrogel according to claim 1, for use in the treatment of incontinence.
- 7. (Currently amended) The hydrogel according to claim 42, further comprising at least 75% by weight pyrogen free-water or saline solution.

Serial No.: 09/938,667

667 Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE

AND VESICOURETAL REFLUX

Page 3 of 13

8. (Cancelled)

9. (Currently amended) A method of treating incontinence or vesicouretal reflux comprising

administering a hydrogel to a mammal, said hydrogel comprising about 0.5 to 25% by weight,

polyacrylamide-based on the total weight of the hydrogel, of a polymer prepared by combining

acrylamide and methylene-bis-acrylamide and is substantially free of monomeric units wherein

said hydrogel includes less than 50 ppm monomeric units.

10. (Original) The method according to claim 9, wherein the hydrogel is obtainable by

combining acrylamide and methylene-bis-acrylamide in a molar ratio of 150:1 to 1000:1.

11. (Currently amended) The method according to claim 9, wherein the hydrogel comprises less

than 15% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

12. (Currently amended) The method according to claim 11, wherein the hydrogel comprises at

least 1% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

13. (Previously presented) The method according to claim 9, wherein the hydrogel has a complex

viscosity of about 2 to 40 Pas.

14. (Currently amended) The method according to claim 9, wherein the hydrogel comprises at

least 80% by weight pyrogen-free-water or saline solution.

15. (Original) The method according to claim 9, wherein the administering comprises injecting

the hydrogel.

16. (Previously presented) The method according to claim 15, wherein the injecting of the

hydrogel comprises injections which include

Serial No.: 09/938,667

Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE

AND VESICOURETAL REFLUX

Page 4 of 13

injections at positions 10, 2, and 6 o'clock of the cross-sectional axis of the urethra for the

treatment of urinary incontinence;

injections at positions 10, 2, and 6 o'clock of the cross-sectional axis of the colon or rectum for

the treatment of anal incontinence; or

injections at positions 10, 2, and 6 o'clock of the cross-sectional axis of the ureter for the

treatment of vesicouretal reflux.

17. (Previously presented) The method according to claim 9, further comprising the inclusion of

cells.

18. (Currently amended) A prosthetic device for increasing the resistance of conduits comprising

a urethra, a rectum, a colon, or a ureter wherein said device is injectable and comprises a

hydrogel as defined in any of claims 1 to [[8]] 7.

19. (Previously presented) The device according to claim 18, further comprising cells.

20. (Currently amended) The hydrogel according to claim 1, comprising less than 10% by weight

polyaerylamide of the polymer, based on the total weight of the hydrogel.

21. (Cancelled)

22. (Cancelled)

23. (Currently amended) The hydrogel according to claim 1, comprising less than 3.5% by

weight polyaerylamide of the polymer, based on the total weight of the hydrogel.

24. (Currently amended) The hydrogel according to claim 1, comprising at least 1.5% by weight

polyaerylamide of the polymer, based on the total weight of the hydrogel.

Serial No.: 09/938,667

Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE

AND VESICOURETAL REFLUX

Page 5 of 13

25. (Cancelled)

26. (Previously presented) The hydrogel according to claim 1, having a complex viscosity of

about 2 to 30 Pas.

27. (Cancelled)

28. (Currently amended) The biostable hydrogel composition of claim 42, wherein washing is

done with pyrogen free water.

29. (Currently amended) The method according to claim 9, wherein the hydrogel comprises less

than 10% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

30. (Currently amended) The method according to claim 9, wherein the hydrogel comprises less

than 7.5% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

31. (Currently amended) The method according to claim 9, wherein the hydrogel comprises less

than 5% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

32. (Currently amended) The method according to claim 9, wherein the hydrogel comprises less

than 3.5% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

33. (Currently amended) The method according to claim 9, wherein the hydrogel comprises at

least 1.5% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

34. (Currently amended) The method according to claim 9, wherein the hydrogel comprises at

least 1.6% by weight polyacrylamide of the polymer, based on the total weight of the hydrogel.

Serial No.: 09/938,667

Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE

AND VESICOURETAL REFLUX

Page 6 of 13

35. (Previously presented) The method according to claim 9, wherein the hydrogel has a complex

viscosity of about 2 to 30 Pas.

36. (Previously presented) The method according to claim 9, wherein the hydrogel has a complex

viscosity of about 2 to 20 Pas.

37. (Previously presented) The method according to claim 17, wherein the cells comprise stem

cells.

38. (Previously presented) The method according to claim 17, wherein the cells allow for cellular

engraftment to the surrounding tissue in the ureter, urethra or analis canalis.

39. (Previously presented) The device according to claim 19, wherein the cells include stem

cells.

40. (Previously presented) The device according to claim 19, wherein the cells allow for cellular

engraftment to the surrounding tissue in the ureter, urethra or analis canalis.

41. (Previously presented) The device according to claim 18, wherein the device increases the

resistance of the urethra to treat urinary incontinence, increases the resistance of the rectum or

colon to treat anal incontinence or increases the resistance of the ureter to treat vesicouretal

reflux.

42. (Currently amended) The hydrogel according to claim 1 which is made under the conditions

of radical initiation and washing with pyrogen free water or saline solution.

43. (Currently amended) The hydrogel according to claim 42 comprising at least 85% by weight

pyrogen-free-water or saline solution.

Serial No.: 09/938,667 Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE

AND VESICOURETAL REFLUX

Page 7 of 13

[[43]]44. (Currently amended) The hydrogel according to claim 1 comprising at least 90% by

weight pyrogen free water or saline solution.

45. (Currently amended) The hydrogel according to claim 1 comprising at least 95% by weight

pyrogen-free water or saline solution.

46. (Previously presented) The hydrogel according to claim 1, having a complex viscosity of

about 2 to 50 Pas.

47. (Previously presented) The method according to claim 9, wherein the hydrogel has a

complex viscosity of about 2 to 50 Pas.

48. (New) The hydrogel according to claim 1, wherein incontinence is selected from the group

consisting of urinary and anal incontinence.

49. (New) The method according to claim 9, wherein incontinence is selected from the group

consisting of urinary and anal incontinence.

Support for the amendments may be found throughout the application as originally filed,

for instance on page 7, lines 5-8, and in the claims as originally filed.